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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,055	12/27/2001	Ronald M. Burch	200.1079CON	7860

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/033,055	**Applicant(s)** BURCH ET AL.	
	Examiner Sue Liu	**Art Unit** 1639	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *38 and 47-56*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation Sheet

Item 3

1. Applicants' proposed amendments to the claims have changed the scope of the claimed invention. The instant claimed scope has changed from the open or partially open "consisting essentially of" to the closed "consisting of", which will require new search and consideration.

Applicants also amended the claims to recite "a ... dosage form comprising two analgesic compounds" (emphasis added), which has narrowed the scope of the invention to two compound from a broad claim of a genus of dosage forms that can comprise different numbers of analgesic compounds. This changing in scope of the claim will require new search and consideration.

The proposed amendments to the claims will also require new consideration such as issues under 35 USC 112, 2nd paragraph. For example, the proposed amendments to the claim (Claim 38) could render the claim indefinite, because it is not clear exactly what entities (or compounds) constitute the claimed oral dosage form.

Item 11.

2. Applicants amendments to the claims and accompanying arguments do not overcome the following rejections:

A.) Claims 38, 47-48, and 50-56 as amended or originally filed are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,569,937 (Baker et al) and Penning et al (J. Med. Chem. 1997, 40, 1347-1365).

B.) Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. '937 and Penning et al as applied to claims 38, 46-48 and 50-56 above, and further in view of Oshlack et al. US Pat. No. 5,472,712 (12/95) or Oshlack et al. US Pat. No. 6,294,195 (9/01: effectively filed 10/93 or earlier).

Applicants' amended the claim (Claim 38) to recite "consisting of" to limit the claimed analgesic compounds in the oral dosage form to celecoxib and oxycodone, and their pharmaceutically acceptable salts. However, the transitional phrase "consisting of" does not modify the "oral dosage form", which can comprise other ingredients besides the analgesic compounds. Furthermore, the claimed method of treatment is also not close-ended because the transitional phrase "comprising". Thus, the instant claim is drawn to a method of administering an oral dosage form, which may "comprise" two analgesic compounds (that are consisting of celecoxib and oxycodone) and other ingredients.

Applicants also assert that applicants' arguments did not address the references individually. However, applicants' argument filed 10/30/06 only seems to discuss the references individually. Applicants discussed the Baker reference alone from p. 6 to top of p. 11 of the Reply, 10/30/06. Although applicants discussed the Penning reference (Reply, p. 11, last two para), applicants did not consider the two references as a combination for the obviousness rejection.

Applicants seem to argue that because each one of the references (Baker or Penning) does not teach all elements of the claimed invention individually, there is no motivation to combine

the references. However, the obviousness rejection is based on the combination of references (Baker and Penning).

Applicants also argue that the Baker reference teaches away from the claimed invention. In support of this argument, applicants state that a reference (Sunshine) cited by the Baker reference does not teach celecoxib as a NSAID, and thus the Baker reference teaches away or provides no motivation to use celecoxib. However, the obviousness rejection as set forth in the previous Office action is based on the combination of the Baker and the Penning references, not a combination of Baker and Sunshine. The Sunshine reference only offers examples of prior art's teaching. It does not, on the other hand, teach away from other analgesic drugs that are known in the prior art that can be combined with a narcotic analgesic (such as oxycodone).

Contrary to applicants' assertion, the Baker reference clearly teaches combining a narcotic analgesic and a NSAID drug (e.g. Col. 1, lines 20+). The Baker reference also clearly teaches the motivation to combine a narcotic analgesic and a NSAID drug. For example, the Baker reference states "the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone" (col. 1, lines 23-25). This provides ample motivation for a person of ordinary skill in the art to combine a selected NSAID and a selected narcotic analgesic drug to achieve a greater effect.

Furthermore, the Baker reference also teaches the preferred narcotic analgesic is oxycodone, as discussed in the previous Office action, mailed 7/28/06, p. 11, para 3+). The Baker reference does not specifically teach that celecoxib (a NSAID equivalent) is combined with oxycodone. However, Penning et al teach a NSAID equivalent, celecoxib, which has less

side effects than NSAIDs, and also offers other advantages such as good bioavailability and potency in pain killing. Thus, a person of ordinary skill in the art would have been motivated at the time the invention was made to combine oxycodone and celecoxib as a combination of analgesic compounds to achieve the greater additive effects.

JON EPPERSON, PH.D.
PATENT EXAMINER